IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' REPLY IN SUPPORT OF MOTION
TO EXCLUDE THE TESTIMONY OF DR. DUANE PRIDDY, PH.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this Reply in Support of their Motion to Exclude the Testimony and Opinions of Dr. Duane Priddy, Ph.D. [Doc. # 1988 ("Motion")] and Memorandum of Law in Support [Doc. # 1989 ("Mem. in Supp.")]. Ethicon requests that the Court grant its Motion and reject the arguments raised in Plaintiffs' Response to the Motion [Doc. # 2168 ("Response")] because any conclusions about degradation made from Dr. Priddy's testing of molten Prolene at 100% oxygen or 100% nitrogen and 300º F above the human body temperature, which could introduce new degradation reactions, are not relevant to the issue in this case—whether or not Prolene meshes degrade *in vivo*.

I. Dr. Priddy's Testing Is Unreliable and Not Relevant to This Litigation.

In the Motion, Ethicon explained that Dr. Priddy's testimony is unreliable and not relevant to this litigation because it was conducted

(i) under conditions that have no relationship to the human body, and

(ii) on mesh samples that have substantially different structures and physical properties than the Ethicon mesh products used in patients.[1]

See Mem. in Supp. at 4–6. Because there is no scientifically legitimate correlation between Dr. Priddy's testing and the Ethicon mesh products under *in vivo* conditions, Ethicon argued that exclusion of Dr. Priddy's opinions based on this testing is consistent with this Court's decisions regarding similar testing. *See id.* at 6 (discussing this Court's exclusion of Dr. Mays's opinions based on TGA testing in *Frankum v. Boston Sci. Corp.*, No. 2:12-cv-0904, 2015 WL 1976952, at **14–15 (S.D. W. Va. May 1, 2015)).

Dr. Priddy admitted under oath that his testing conditions, at 300° F above the normal temperature for a human body and subject to conditions of 100% nitrogen or 100% oxygen, far exceed anything that pelvic mesh products could ever encounter in the human body. Mem. in Supp. at 4. Although Plaintiffs concede that Dr. Priddy's testing did not replicate the human body and "was performed at several hundred degrees above human body temperature" (Resp. at 6), they ask this Court to permit Dr. Priddy to opine that his testing of molten Prolene shows how long Prolene's antioxidants would protect the mesh inside the human body. Plaintiffs' Response, of course, did not address Dr. Priddy admission that heat-based aging tests could "introduce new degradation reactions," his failure to show that the molten Prolene behaves the same as solid-state Prolene in the human body, or his failure to investigate the impact of those new reactions on his test results. *See* Mem. in Supp. at 6.

Instead, Plaintiffs Response brushes over these failures and claims that Dr. Priddy's tests are relevant because he "correlated" his test data regarding molten Prolene to determine how

[1] Despite Plaintiffs' bizarre assertion that Ethicon "does not challenge any of Dr. Priddy's opinions" (Resp. at 2), Ethicon's Motion clearly seeks to exclude Dr. Priddy's testimony from this litigation.

long the antioxidants in Prolene can last *in vivo* by "us[ing] two ASTM industry standards" that purportedly "correlate to each other." Resp. at 5–6. Plaintiffs Response does not show why it is appropriate to "correlate" test results of molten Prolene to predict reactions in the human body. *See* Response at 6.

In defense of this correlation, Plaintiffs assert that Dr. Priddy used ASTM D3895 to conduct oxidative induction time ("OIT") testing to determine the mesh's "resistance to oxidative decomposition" (Resp. at 4) and "used [the data from that testing] with ASTM F1980's accelerated aging testing's protocol to determine how long the antioxidants would protect the mesh inside the body." *Id.* at 5–6. On closer inspection, Dr. Priddy's use of and reliance on them is fraught with problems.

Dr. Priddy's sworn testimony admits that he did not follow ASTM 1980 because ASTM 1980 "is specific to packaging for medical devices." Resp. Ex. E, Priddy 3/8/16 Dep. Tr. at 24:7–8; *see also* Reply Ex. F, ASTM F1980-02, *Standard Guide for Accelerated Aging of Sterile Medical Device Packages*. Dr. Priddy only used one of ASTM 1980's protocols — "Q10 protocol," which assumes that an oxidation rate doubles with every 10 degrees Centigrade.

Plaintiffs' argument that Dr. Priddy "correlated" his test data to *in vivo* conditions using ASTM 1980 is belied by Dr. Priddy's own words:

Q. And you followed the protocols from the ASTM D3895 and ASTM 1980, correct?

. . .

A. 1980, no, I did the ASTM D3895.

. . .

Q. Did you follow the protocols from the ASTM 1980?

A. I would say no. The 1980 is specific to packaging for medical devices, so I didn't, since this was not packaging for a medical device, I did not follow that.

Resp. Ex. E, Priddy Dep. 3/8/16 Tr. 23:24-24:10; *see also id.* at 24:11-25:18 (explaining that his use of ASTM 1980 was limited to following its "Q10 protocol," which assumes that an oxidation rate doubles with every 10 degrees Centigrade). In other words, Dr. Priddy selected a single protocol from an otherwise irrelevant standard for *medical packaging* so that he could apply an oxidation rate that doubles with every increase of 10 degrees Centigrade to his tests on super-heated, molten samples of Prolene.

Plaintiffs' defense of Dr. Priddy's use of ASTM 3895 is equally unavailing. Despite Plaintiffs' unsupported assertions to the contrary (Resp. at 4, 7), Ethicon's Motion explained that Dr. Priddy did not adhere to the protocol defined by ASTM 3895 because he failed to abide by ASTM 3895's sample preparation procedures, including keeping a record of his sample preparation process so his testing methodology could be assessed. Mem. in Supp. at 9–10. Even if Dr. Priddy had followed ASTM 3895, his testing would have no relationship to the human body.

Plaintiffs make no effort to address the disparities between Dr. Priddy's OIT testing and Ethicon's mesh products as they are used in patients. *See* Mem. in Supp. at 4–6. Indeed, Plaintiffs concede that Dr. Priddy's OIT testing was "[i]n no way . . . meant to directly replicate the body's *in vivo* environment[.]" Resp. at 6. But Plaintiffs do not acknowledge—much less address—Ethicon's detailed explanation as to why Dr. Priddy's OIT testing is unreliable and speculative, particularly in the context of Ethicon mesh products. *See* Mem. in Supp. at 7–9. Therefore, the Court should exclude his opinions based on this testing because Dr. Priddy's OIT

testing bears no relationship to the human body and he cannot justify the correlation of his test results to *in vivo* conditions.[2]

II. Dr. Priddy's Opinions Are Not Based on a Reliable Scientific Methodology.

As Ethicon explained in its Motion, even if Dr. Priddy's testing was relevant and reliable in the context of Ethicon's mesh products, the manner in which Dr. Priddy actually conducted the testing in this litigation demonstrates that his opinions based on that testing should be excluded as methodologically unsound.

A. Dr. Priddy deviated from his testing protocol.

In the Motion, Ethicon explained that Dr. Priddy failed to adhere to his own testing protocol by deviating from the sample preparation procedures identified in ASTM 3895. Mem. in Supp. at 9. Dr. Priddy could provide no scientific rationale for his deviations from the protocol. *Id.* Ethicon also showed that Dr. Priddy's failure to maintain a written record of his sample preparation process precludes assessment of his methods. *Id.*

Plaintiffs' Response does not rebut these arguments. Resp. at 7. Instead of addressing Dr. Priddy's failures to follow the ASTM protocol (Mem. in Supp. at 9), Plaintiffs incorrectly assert that Dr. Priddy followed the protocol "to the letter" and that there is "no evidence" of any deviations (Resp. at 4, 7).

B. Dr. Priddy did not use a control.

"Vigorous adherence to protocols and controls are the hallmarks of 'good science.'" Sanchez v. Boston Sci. Corp., No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Oct. 17, 2014). As Ethicon explained in the Motion, Dr. Priddy conducted two tests. The first was OIT testing that should have used a control to determine if the specimen holder influenced the test

[2] Although Plaintiffs attempt to distinguish Dr. Priddy's opinions from Dr. Mays's unreliable opinions that were excluded by this Court in *Frankum*, (Resp. at 10–11), Plaintiffs' arguments fail for the same reasons.

results, as required by ASTM 3895. The second was GC/MS testing that should have used a sample of pure polypropylene to determine whether methylene chloride and sonication affect the polypropylene component of Prolene. Without these critical controls as part of his experiments, Dr. Priddy cannot validate his methodology. Mem. in Supp. at 10. Plaintiffs fail to even address the need for a specimen holder as a control. As for the OIT testing, curiously Plaintiffs assert that "there was no need" for Dr. Priddy to use a control because Dr. Priddy used a "known" value for pure polypropylene as his control. Resp. at 7. But Plaintiffs' claim has no support in the record, and even the materials Plaintiffs cite belie their assertion. *See* Resp. at 7 (citing Priddy Report at 3-4 & Fn.3-6; Priddy 3/8/2016 Dep. Tr. 84:2-13).

Nowhere in Dr. Priddy's Report—including the pages Plaintiffs cite—does he claim that he used any form of a control. In addition, the deposition testimony Plaintiffs cite is the very same excerpt identified in Ethicon's Motion, which reveals that Mr. Johnson merely ran an "internal standard" through his gas chromatography-mass spectroscopy ("GC/MS") machine to determine whether the "equipment is operating." Mem. in Supp. at 10 (citing Priddy 3/8/2016 Dep. Tr. 84:2-13). Although Ethicon does not dispute the importance of calibrating testing equipment, Mr. Johnson's efforts do not constitute an experimental control, and do not explain Dr. Priddy's OIT testing. Thus, it is clear that Dr. Priddy failed to use a control to ensure that his testing methods did not introduce error into his results.

Furthermore, Plaintiffs' suggestion that Dr. Priddy could have simply used a value for pure polypropylene from prior ASTM testing indicates that they misunderstand Ethicon's argument. Dr. Priddy conducted OIT testing, purportedly in accordance with ASTM 3895, but he also performed GC/MS analysis on antioxidants he extracted from the samples using a methylene chloride solvent and sonication. *See* Mem. in Supp. at 1-2, 10-11. Dr. Priddy's failure

to use a control in connection with his GC/MS analysis means that he cannot rule out the introduction of error through the OIT testing, the antioxidant extraction process, or the GC/MS testing itself. *Id.* at 10-11.

Thus, even if Dr. Priddy did use a "known" value for his ASTM testing—and the evidence shows he did not—he still failed to use a control to validate his antioxidant extraction and GC/MS testing methodology. The Court should exclude Dr. Priddy's opinions for these reasons.

C. Dr. Priddy lacked a sufficient understanding of his testing in this litigation.

Ethicon argued in its Motion that the Court should exclude Dr. Priddy's testimony because he had insufficient knowledge of the actual testing process on which his opinions are based. Mem. in Supp. at 11–12. Specifically, Ethicon explained that Dr. Priddy's opinions are inconsistent with the requirements of Federal Rule of Evidence 702 because he could not answer basic questions regarding the methodology used in the testing, and failed to produce the lab report that allegedly contained all of the information regarding the methodology. *Id.*

Plaintiffs deflect Ethicon's argument by claiming that Dr. Priddy should be permitted to testify about his testing since he "spent his career performing tests like the one he did for his report," and he "chose this testing based on the fact that it was standard plastic-industry practice." Resp. at 7. However, Plaintiffs' argument makes no sense and fails to respond to any of Ethicon's specific arguments or the evidence Ethicon identified in support. Indeed, nothing in Plaintiffs' Response or Dr. Priddy's Report or testimony suggests that he had sufficient knowledge of the testing to satisfy Rule 702.

The Court should reject Plaintiffs' non-responsive argument, and exclude Dr. Priddy's testimony in this litigation.

D. Dr. Priddy did not support his opinions with statistical analysis.

Ethicon's Motion explained that Dr. Priddy's testimony is unreliable because he failed to validate his test results through statistical analysis. Mem. in Supp. at 12. Specifically, Ethicon argued that although Dr. Priddy claimed at deposition to have validated his test results using statistical analysis, his Report contained no such analyses. *Id.* (*citing* Priddy 3/8/2016 Dep. Tr. 39:21–40:7).

Paying no attention to Dr. Priddy's testimony, Plaintiffs assert that Ethicon's argument amounts to a "logical fallacy" because statistical analysis would be "impossible." Resp. at 8. Plaintiffs appear to be oblivious that Dr. Priddy testified that he actually conducted such analyses. *See* Mem. in Supp. at 12. Furthermore, Plaintiffs' claim that the purpose of statistical analysis is limited to questions of "sample size," is nonsensical, and should be rejected by this Court.

III. Conclusion

For all of these reasons, as well as those set forth in Ethicon's Motion, Ethicon respectfully requests that the Court grant its Motion to Exclude the Testimony of Dr. Duane Priddy.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 14, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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